UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Note to Reader January 15, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. It is not meant to be a summary of all current information regarding the chemical. Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director

Special Review and Reregistration Division

MEMORANDUM

SUBJECT: Methidathion. Reregistration Case No. 0034, Chemical No. 100301. Follow-up

to Residue Chemistry Chapter of the RED. Anticipated Residues for Acute

Dietary Risk Assessment. CBRS No.17467. DP Barcode D228746.

FROM: William O. Smith, Chemist

Chemistry Pilot Review Team

Chemistry Branch II: Reregistration Support

Health Effects Division (7509C)

THROUGH: R. B. Perfetti, Ph.D., Acting Branch Chief

Chemistry Branch II: Reregistration Support

Health Effects Division (7509C)

TO: John Redden, Chemical Review Manager

Risk Characterization and Analysis Branch

Health Effects Division (7509C)

DRES has identified an unacceptable acute dietary risk for methidathion using the Tier 1 assessment procedures and is requesting anticipated residue information. MOEs are on the order of 1 to 5, based on presently established tolerances for methidathion. MOEs, based on reassessed tolerances, are <1 to 2 (B. Steinwand, personal comm.). The contribution of individual food commodities to acute dietary risk is not available at this time; however, it should be noted that the only tolerance reassessment that would result in lower MOEs was an increase in the citrus tolerance from 2 ppm to 4 ppm. On the other hand the reassessment included revocation of tolerances on potatoes (0.2 ppm); milk (0.03 ppm); and meat, poultry and eggs (0.05 ppm). Essentially all other tolerances on food commodities are set at the limit of detection of the analytical method.

Anticipated residues for purposes of acute dietary risk assessment are provided in Table 1. The source of these data and any assumptions made are described in the following discussion.

Table 1. Methidathion Anticipated Residues for Acute Dietary Risk Assessment

Commodity	Reassessed Tolerance (ppm)	Anticipated Residue (ppm)	Comments
Artichokes	0.05	0.05	
Oranges (exc. Mandarin)	4	-	
peeled fruit/pulp	-	0.33	May be consumed as a single serving. (tolerance on RAC) X (conc. factor for orange pulp)
juice	-	0.26	May be consumed as a single serving. (tolerance on RAC) X (conc. factor for orange juice)
peel	-	0.114	Blended or mixed before consumption. (95th %tile PDP data) X (conc. factor for orange peel)
Grapefruit	4	-	
peeled fruit/pulp	-	0.33	May be consumed as a single serving. Used conc. factor for orange wet pulp.
juice	-	0.26	May be consumed as a single serving. Used conc. factor for orange juice.
peel	-	0.114	Blended or mixed before consumption. (95th %tile PDP data) X (conc. factor for orange peel).
Lemon	4	-	
peeled fruit/pulp	-	0.33	May be consumed as a single serving. Used conc. factor for orange wet pulp.
juice	-	0.001	Blended or mixed before consumption. (95th %tile PDP data on oranges) X (conc. factor for orange juice).
peel	-	0.114	Blended or mixed before consumption. (95th %tile PDP data on oranges) X (conc. factor for orange peel).
Lime	4	-	
peeled fruit/pulp	-	0.33	May be consumed as a single serving.
juice	-	0.001	Blended or mixed before consumption. (95th %tile PDP data on oranges) X (conc. factor for orange juice).
peel	-	0.114	Blended or mixed before consumption. (95th %tile PDP data on oranges) X (conc. factor for orange peel).
Mandarin (Tangerine)	6	-	
peeled fruit/pulp	-	0.49	May be consumed as single serving. (Tolerance) X (conc. factor for orange wet pulp)
Citrus oil	420	3.48	Blended or mixed before consumption. (95th %tile PDP data on oranges) X (conc. factor for orange oil)
Apples	0.05	0.05	May be consumed as a single serving.
juice	-	0.015	Blended or mixed before consumption. 95th %tile from PDP data
Peaches	0.05	0.05	May be consumed as a single serving. Anticipated residues = tolerance.
hulled	-	0.015	Blended or mixed before consumption. 95th %tile PDP data

Commodity	Reassessed Tolerance (ppm)	Anticipated Residue (ppm)	Comments
juice	-	0.015	Blended or mixed before consumption. 95th %tile PDP data
All other pome fruits and stone fruits	0.05	0.05	No expectation of detectable residues in <u>any</u> food form in these crop groups. Anticipated residues = tolerances, which are based on LOD of analytical method.
Cottonseed	0.2	-	
oil	-	0.05	Based on nondetectable residues in a processing study.
Mangoes	0.05	0.05	
Tree nuts	0.05	0.05	No expectation of detectable residues in <u>any</u> food commodity from the tenut group. Anticipated residues = tolerances, which are based on LOD analytical method.
Olives	0.05	0.05	
oil	-	0.05	
Safflower seeds	0.2	-	
oil	-	0.01	Used sunflower processing data as surrogate.
Sunflower seeds	0.5	0.5	
oil	-	0.01	Based on nondetectable residues in a processing study.
Carambola	0.1	0.1	
Kiwi Fruit	0.1	0.1	
Longan	0.1	0.1	
Sugar apple	0.2	0.2	

DISCUSSION

Anticipated residue are estimated in this memorandum using tolerance level residues and survey data from the USDA Pesticide Data Program (PDP). For food forms that are typically mixed prior to consumption, the 95th percentile residue from PDP monitoring data is used as the anticipated residue. The remaining anticipated residues on raw food commodities are set at the tolerance.

Citrus Fruits

A citrus processing study was summarized in the Methidathion Registration Standard - Residue Chemistry Chapter dated 6/30/82. The following paragraph and table are taken from that review. The original data are found in MRID 00011323 (PP#0F0892).

Residue data were presented for methidathion applied at 0.25 lb, 0.5 lb, 1.0 lb, and 2.0 lb of a.i./100 gallons of water by ground equipment. The fruits were sampled for residue analysis at 0,

7, 14, 21, 30 and 45 days after the last application. The data on oranges with 2 applications (winter) and 3 applications (summer-fall) with and without summer oil have been tabulated for the whole fruit and various important fractions as follows:

Table 2. Summary of Residues in whole oranges and orange fractions following treatment with Methidathion

		Methidathion Residues (ppm)							
Day	Rate (lb ai/ 100gal)	Whole fruit (unwashed)	Wet pulp (after wash)	Juice	Peel (after wash)	Dried pulp	Pressed Oil		
Two applications - Florida (Winter)									
30	1/2	1.08	<0.05	<0.05	2.78	0.64	78		
30	1	2.30	<0.05	<0.09	10.0	1.09	158		
45	1/2	0.82	<0.05	<0.05	6.71	0.46	90		
45	1	2.03	<0.05	0.14	12.3	1.23	230		
60	1/2	0.61	<0.05	<0.05	4.14	0.34	65		
60	1	3.47	<0.05	<0.05	14.5	1.27	208		
	Three applications - Florida (Summer/Fall)								
50	1/4 (w/o summer oil)	0.96	0.09	0.05	1.2	0.75	120		
50	1/2 (w/o summer oil)	1.6	0.21	0.13	1.9	2.2	257		
50	1/4 (with summer oil)	1.0	0.18	0.09	1.7	0.68	142		
50	1/2 (with summer oil)	1.9	0.32	0.21	3.3	2.8	376		

In the following table average concentration factors are derived from the processed fractions for purposes of estimating acute anticipated residues.

Table 3. Concentration of Methidathion Residues in Orange Fractions

		Concentration/Reduction factor (residues in fruit/residues in processed fraction)						
Day	Rate (lb ai/ 100gal)	Whole fruit (unwashed)	Wet pulp (after wash)	Juice	Peel (after wash)	Dried pulp	Pressed Oil	
Two applications - Florida (Winter)								
30	1/2	-	0.046	0.046	2.57	0.59	72.2	
30	1	-	0.022	0.039	4.35	0.47	68.7	
45	1/2	-	0.061	0.061	8.18	0.56	109.8	
45	1	-	0.025	0.069	6.06	0.61	113.3	
60	1/2	-	0.082	0.082	6.79	0.56	106.6	
60	1	-	0.014	0.014	4.18	0.37	59.9	
Three applications - Florida (Summer/Fall)								
50	1/4 (w/o summer oil)	-	0.094	0.052	1.25	0.78	125	
50	1/2 (w/o summer oil)	-	0.13	0.081	1.19	1.375	160.6	
50	1/4 (with summer oil)	-	0.18	0.09	1.7	0.68	142	
50	1/2 (with summer oil)	-	0.168	0.111	1.737	1.474	197.9	
Avg. conc. factor-> - 0.082 0.065 3.8 0.747 116					116			

PDP survey data are available for oranges and grapefruit.

During 1993 and 1994 a total of 1315 orange samples were analyzed for methidathion. There were 67 samples (5.1%) with detectable residues. The maximum residue detected was 0.034 ppm. The 95th percentile level is 0.030 ppm.

During 1993 a total of 632 grapefruit samples were analyzed for methidathion. Three samples (0.5%) had detectable residues with a maximum residue of 0.014 ppm. No grapefruit samples were surveyed in 1994. The maximum limit of detection will be used as the 95th percentile, 0.015 ppm.

Pome Fruits, Stone Fruits and Tree Nuts

Methidathion is used as a delayed dormant spray in fruit and nut orchards. Residue data support establishment of the existing crop group tolerances at 0.05 ppm, which is the limit of detection for the residue analytical method used in field trials. Processing studies were not required for any of these crops because of the use pattern and the absence of detectable residues, even in trials conducted at exaggerated rates. There is no expectation of detectable residues in any food commodity derived from uses on crops in these three crop groups.

Some monitoring data are available confirming that residues are nondetectable even at lower LODs. These data are summarized below.

Apples:

PDP survey data are available for apples. In 1994 there were 687 samples analyzed with no detectable residues (LOD = 0.002-0.015 ppm).

Apple juice is blended or mixed before consumption; therefore, acute anticipated residues could be estimated from the 95th percentile residue value from monitoring data on apples. Since there were no detectable residues in these data we will use the maximum limit of detection, which is 0.015 ppm.

The anticipated residue for the fruit, which may be consumed as a single serving, should be estimated as equivalent to the tolerance.

Peaches:

PDP survey data are available for peaches. In 1994 there were a total of 396 samples analyzed; no sample had detectable residues (LODs = 0.002-0.015 ppm).

Peach juice and hulled peaches are blended or mixed before consumption; therefore, the anticipated residues of 0.015 ppm are based on the maximum limit of detection from the

monitoring data.

The anticipated residue for the fruit and any other peach food forms is the tolerance level of 0.05 ppm, since these may be consumed as single servings.

Olives

No processing study was required on olives as residues were nondetectable in field trials, even at exaggerated use rates. Detectable residues are not expected in olive oil.

Cotton

A cotton processing study was summarized in the Methidathion FRSTR - Residue Chemistry Chapter dated 6/7/88. Residues were nondetectable in refined oil.

Sunflower and Safflower

A sunflower processing study was summarized in the Methidathion FRSTR - Residue Chemistry Chapter dated 6/7/88. Residues were nondetectable in the oil. In the absence of data on safflower oil we recommend using the sunflower data as a surrogate.

CBRS has recommended revocation of tolerances on meat, milk, poultry, eggs, and potatoes; therefore, no residues are anticipated on these food commodities.

cc: Reviewer(W. Smith), Reg. Std. File, RF, SF, Circ.

RDI:Pilot Team:12/02/96:RPerfetti:12/03/96

7509C:CBRS:CM#2:Rm805A 305-5353:WSmith:12/02/96